



AUTHORISATION GUIDELINES FOR NUCLEAR GAUGES

Facilities and activities using radioactive material need to be authorized by the Radiation Protection Agency (RPA) in accordance with the provisions of the Radiation Protection Agency Act 2018. Section 18(1) of the Radiation Protection Agency Act, states that a person shall not carry out an activity or practice involving ionizing radiation, import or export a radiation source, radioactive source or nuclear material unless he is issued a license or authorization by the Radiation Protection Agency or unless the activity is removed from the regulatory control.

AUTHORISATION GUIDELINES

These guidelines apply to facilities using nuclear gauges. They have been developed to provide a detailed description of the information and documentation that must be submitted to RPA during the authorization process for review and assessment of compliance with the regulatory requirements. In order to ensure compliance with the Radiation Protection Agency Act 2018, any individual or organization who intends to use nuclear gauges in the facilities should satisfy the requirements of the authorisation process.

For authorisation, an applicant shall submit documents as per these guidelines as attachments to the application form.

Step 1. Notification

Notification is required for facilities or activities intending to use nuclear gauges where the legal person is to demonstrate justification of the practice. The legal person or facility should obtain and complete the notification form from the RPA offices or at www.rpa.org.ls prior to full application.

Step 2. Application for authorisation

GENERAL INFORMATION

General information should be completed as per the application form.

ADMINISTRATIVE INFORMATION

In the application, clearly provide the following information

1. Legal person; Specify the formal name of the applicant. (*A legal person can be any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, person/individual having an authority over a facility/activity*).
2. Address of head office; Specify the address of the headquarters of the legal person.
3. Name and title of the representative of the legal person (Head of the Institution).
Specify the name and title of the representative of the legal person.
4. Location(s) of the practice. Specify the address(es) of the practice.
 - a. Telephone number;
 - b. Email address
5. Contact details of the radiation protection officer(s). Specify the details of the radiation protection officer(s) to be contacted with respect to the authorization:
 - a. Telephone number;
 - b. Email address.
6. Endorsement of application (the application must be signed by the representative of the legal person):
 - a. Name;
 - b. Signature;
 - c. Date;
 - d. Official stamp/seal.

The supporting documents that must be submitted as attachments to the application for authorization should cover the following:

INTEGRATED MANAGEMENT SYSTEM

1) **Management structure and responsibilities.** Describe overall organizational structure and integrated management system ensuring that protection, safety, and security are effectively incorporated into the overall management system of the applicant. Describe and clearly define responsibilities for radiation safety and security for the following parties as appropriate:

- Management of the Facility
- Radiation Protection Officer(s)
- Person(s) responsible for security (advisers, guards and other security related positions)
- Workers, itinerant workers
- Responsibilities for cooperation and consultation

2) **Verification of compliance.** Describe the regular assessment of protection, safety and security, such as a quality control programme and plans for regular reviews.

3) **Submission of the following documentation including procedures and programmes to the RPA as applicable:**

- (a) Radiation source inventory, supplier of sources, prior assessment of radioactive sources and inventory of disused sources;
- (b) Educational qualifications, training and competence of the staff and their retraining (attach educational qualifications and training certificates);
- (c) Testing, routine and periodic examination and maintenance, and quality assurance programme;
- (d) Investigation of incidents and accidents;
- (e) Emergency preparedness and response measures;
- (f) Control of modification(s) of facilities, equipment and activity;
- (g) Management of disused sources and depleted uranium, if applicable
- (h) Safe transport of radiation sources
- (i) Controlled import and export of radioactive sources
- (j) Programme for the improvement of the integrated management system

TECHNICAL INFORMATION FOR NUCLEAR GAUGES

(1) Information on radiation sources.

(a) Information on nuclear gauge(s) containing radioactive sources, i.e. the housing of radioactive sources:

- (i) Manufacturer of the nuclear gauge.
- (ii) Supplier of the nuclear gauge.
- (iii) Model of the nuclear gauge.
- (iv) Serial number of the nuclear gauge

(v) Design, manufacturing and testing of nuclear gauges. Demonstrate that nuclear gauges containing radioactive sources and ancillary equipment are obtained from an authorized manufacturer in accordance with the manufacturer's ISO 9001 quality assurance system (ISO 9001:2015) to ensure that the design safety features are reproduced consistently. Demonstrate that international or national standards are met; e.g. for gauges designed for permanent installation, ISO 7205:1986 applies.

(b) Information on radioactive sources (all non-exempt sources, including sources for checking equipment and calibration sources):

(i) Radionuclide.

(ii) Manufacturer of the source.

(iii) Model.

(iv) Source serial number.

(v) Source activity and reference date.

(vi) Supplier of the source.

(vii) Special form certificate. Attach the special form certificate for the radioactive source. Design, manufacturing and testing of the source. Demonstrate that the design, manufacturing and testing of the source were conducted in accordance with ISO 2919:2012 or another appropriate standard.

(viii) Leak test. Demonstrate that the leak test was conducted in accordance with ISO 9978:2020 or another appropriate standard.

(ix) Working life of the source. Specify the recommended working life given by the manufacturer.

(x) Certificate for sealed radioactive sources, according to ISO 2919:2012 or equivalent standard, specifying: source classification, model designation, serial number, content activity, leak test results according to ISO 9978:2020, radiation output, special form approval certificate number and recommended working life.

(c) Details about depleted uranium used for gauges, sources changers and storage containers, if any:

(i) Specify whether depleted uranium is used;

(ii) Specify the mass of the depleted uranium.

(d) Source changers and storage containers:

(i) Dose levels requirements and labelling requirements. Demonstrate that the source changers and storage containers meet dose levels and labelling requirements to ensure safety.

(ii) Safety of changers and storage containers. Demonstrate the existence of a locking mechanism and that the source changer storage container has been designed so that a source cannot fall out of the container.

(e) Information on X ray generator(s):

(i) Type of the X ray generator.

(ii) Manufacturer of the X ray generator.

(iii) Model of the X ray generator.

(iv) Serial number(s) of the X ray generator housing and panel.

(v) Supplier of the X ray generator.

(vi) Type, model and serial number of the tube.

(vii) Manufacturer of the tube.

(viii) Maximum voltage.

(ix) Maximum current intensity.

- (x) Supplier of the tube.
- (xi) Permanent and added filters. Provide information on the use of filters already installed in the equipment and filters installed by the user.
- (xii) Collimators. Provide information on the use of collimators.
- (xiii) Maximum leakage radiation. Specify the leakage radiation given by the manufacturer.
- (xiv) X - ray generator equipment. Demonstrate that appropriate labels are posted, e.g. on the control panel. Demonstrate that the control panel has safety features, e.g. emergency stop button, appropriate indicators of the status of the equipment and a lock to prevent unauthorized use, and that there is a signal indicating when irradiation is taking place.

(2) Description of the facility.

(i) *Radioactive source storage:*

Layout of the storage for nuclear gauges containing radioactive sources.

Demonstrate that the design of the storage enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the storage characteristics, e.g. entrances, doors, roof, floors, penetrations and adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be stored in the storage area. Specify the maximum capacity of the storage.

(ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. workload and occupancy factor), took into account the radiation fields produced by all sources to be stored. Demonstrate that doses are below dose limits, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.

(iii) Safety features. Specify the position of all technical safety systems, e.g. monitors, sensors, access control measures, barriers, detectors producing warning signals and notices. Describe the design and function of safety and warning systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the radioactive source storage.

(iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.

(b) *Facility with fixed, i.e. installed, nuclear gauges:*

(i) Layout of the facility. Demonstrate that the location of a fixed nuclear gauge enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the characteristics of the facility and adjacent areas, e.g. workplaces and access paths to the gauge. Include details related to the control room, where applicable, and to all other adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be used in the areas and provide the process flow diagram for each area. Give the position(s) of all source(s) and equipment in the facility.

(ii) Shielding calculation and assumptions used. Demonstrate that, during the design of any required shielding barriers, the appropriate assumptions were used (e.g. use factor and occupancy

factor), and the radiation fields produced by a gauge, including scattered radiation, were taken into account. Provide dose and dose rate calculations related to the exposure for workers (in particular those working in places adjacent to the nuclear gauges) and members of the public. Demonstrate that doses are below the dose limit, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.

(iii) **Safety features.** Specify the position of all technical safety features and warning systems, e.g. use of key control, barriers, protective cage and warning signals (i.e. acoustic and visual) and notices. Describe the design and function of safety and warning systems, including the independence, redundancy and diversity of safety systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the installed gauge. Specify how fire protection manages hazards related to the existing radioactive sources. Demonstrate that good engineering practices are taken into account.

(iv) **Boundaries of controlled and supervised areas.** Demonstrate that controlled and supervised areas are designated and attach a layout showing the controlled and supervised areas.

(c) **Locations for site works using nuclear gauges.** Specify in detail how a work with portable gauges will be prepared, e.g. cooperation with the client, assessment of the location, preparation of time schedule, use of local rules and emergency preparedness procedures, taking into account any additional risks at the site. Specify in detail how work with portable gauges will be conducted, e.g. establishment of controlled areas, use of temporary shielding, use of warning signals and notices in a language understood by persons at the location, establishment of all other precautions before, during and after the use of a gauge. Specify the use of all sources and equipment to be available at the site, such as monitoring equipment, personal dosimeters and alarm dosimeters, warning signals and notices, and emergency kit. Demonstrate that radiation monitors are used. In particular, demonstrate that a radiation monitor is used after each exposure using radiation sources. Demonstrate that security is ensured. Demonstrate that arrangements are in place for the transport of radioactive sources. Specify the safety training provided to drivers, as well as data related to the vehicles to be used.

(d) **On-site radioactive source storage.** In on-site works using nuclear gauges, provide procedures requiring appropriate arrangements to be established with the site operator ensuring that the same level of protection as in the user's source storage is granted at the temporary on-site source storage in the operating organization's main base. Describe the basic elements of the layout of a typical temporary storage of radioactive sources in remote locations and specify the maximum capacity of the storage. Demonstrate that doses are to be kept below dose limits, dose constraints for workers and member of the public are established, and doses are optimized to be as low as reasonably achievable possible. Demonstrate that controlled and supervised areas are to be designated. Demonstrate that a qualified expert was involved in the calculations. If the vehicle transporting nuclear gauges is to be used as temporary storage of radioactive sources, specify all safety and security systems, as well as the assumptions used in the assessment of exposures of workers and members of the general public. Demonstrate that controlled and supervised areas are to be designated.

(3) Technical information of radiation monitoring equipment.

(a) **Portable survey meters.** Provide technical information related to portable survey meters to be

used. Demonstrate the suitability and calibration of portable survey meters and specify their number. **(b) Personnel monitoring devices.** Demonstrate that personnel dosimetry devices have been provided to workers. Demonstrate that personal dosimetry devices with direct reading and alarm functions are available. Specify all technical information and dosimetry services to be used.

(4) Safe and secure management and control of radiation sources once it has been decided to take them out of use, including financial provisions, when appropriate. Demonstrate that all disused sources, including depleted uranium, are managed in line with safety requirements, e.g. demonstrate that storage for disused sources is designed and controlled using optimization and dose limitations and that management of the storage includes all safety and security precautions. When appropriate, specify financial provisions for the safe management of all disused sources, including depleted uranium.

SAFETY ASSESSMENT

A safety assessment report that addresses the following aspects:

- (1) Expected doses (occupational and public exposure) arising from normal operation of the practice.
- (2) Estimation of the potential doses (occupational and public) from anticipated operational occurrences and accident conditions (failures or internal or external events that challenge the safety of the facility or activity).
- (3) Identification of postulated accident initiating events, commensurate with the particular features of the practice.
- (4) Description of the severity of the potential consequences for workers and members of the public associated with each of the accident initiating events. Provide an evaluation of the consequences for workers and members of the public based on the potential effect that each accident initiating event could have without taking into account the safety measures or barriers envisaged.
- (5) Description, for each accident initiating event, of existing safety barriers aimed at preventing or mitigating accidents.
- (6) Risks associated with each accident initiating event. Risk needs to be expressed as a function of the frequency with which the initiating event occurs, the robustness of the safety barriers and the severity of the potential consequences associated with each initiating event. Risk may be classified following a prioritization principle to facilitate further decision making.
- (7) Conclusions. Include a programme of safety measures to be carried out for higher risk initiating events to ensure optimization of protection to the highest reasonably achievable safety level.
- (8) Independent verification. Attach the results of an independent verification of the safety assessment.
- (9) Review of safety assessment. Demonstrate that regular and documented reviewing of the safety assessment is in place.

PROTECTION OF WORKERS

- (1) **Education and training of occupationally exposed workers.** Specify names, educational qualifications, training and retraining of workers (including assistants and trainees). Specify whether the Radiation Protection Officer (RPO) complies with the criteria established by the regulatory body, e.g. education, training and experience (attach the appointment letter giving the RPO the authority to stop any unsafe operations). If the applicant uses a qualified expert, provide

information on the certification (formal recognition), education and experience of the qualified expert.

(2) **Personal dosimetry.** Specify the authorized dosimetry service (e.g. RPA) and the arrangements related to the monitoring of personal doses. Provide the records of past occupational exposure of workers (including itinerant), if not already recorded in the registry of occupational doses.

(3) **Workers' health surveillance.** Specify programmes for health surveillance.

(4) **Itinerant workers.** Describe the allocation and documentation of the responsibilities of the employer and the applicant for the safety and protection of itinerant workers.

(5) **Arrangements for the radiation protection programme.** Demonstrate that all of the following elements of the radiation protection programme are in place:

(a) ***Assignment of responsibilities for the radiation protection programme.***

(b) ***Designation of controlled or supervised areas.*** Specify the designation of controlled and supervised areas using a safety assessment and measured dose rates in working rooms or areas and storages. Demonstrate the appropriate management of labels, marks and notices.

(c) ***Practice specific local rules.*** Demonstrate that local rules applicable for workers are prepared for all processes and that an adequate number of workers is involved in the practice. In particular, specify the roles and responsibilities of workers and demonstrate that processes are supervised. Demonstrate that rules, labels and notices are written in a language understood by those for whom they are intended. Provide a workplace and area monitoring programme. Demonstrate that the necessary radiation monitoring equipment is available. Provide the technical specification, selection, calibration, maintenance, testing and use of radiation monitoring equipment. Demonstrate that the monitoring programme takes into account all processes of the applicant, e.g. use and maintenance of radiation equipment, accepting packages with new radiation sources and preparing packages for transport.

(d) ***Personal protective equipment.*** Demonstrate that the need to rely on administrative control and personal protective equipment for protection and safety is minimized, giving priority to engineering controls. Demonstrate that appropriate personal protective equipment i.e thyroid shields, lead aprons, safety goggles is provided and arrangements are made for its proper use, testing and maintenance.

(e) ***Recording and reporting of information.*** Describe the system for recording and reporting all information related to exposure control, decisions regarding measures for occupational radiation protection and safety, as well as individual radiation monitoring.

(f) ***Audit and review of the radiation protection programme.*** Specify methods for periodic auditing and review of the implementation of the radiation protection programme.

Local rules

(i) **Use of gauges.** Demonstrate that local rules include, among others, the installation or dismantling of fixed gauges, maintenance and periodic leak testing of radioactive sources, periodic maintenance and testing of equipment, labelling and posting, use of radiation monitors, security and control of records. Demonstrate that for all activities local rules exist to ensure safe management of radiation sources.

(ii) **Radioactive source storage and on-site radioactive source storage.** Demonstrate that local rules include, among others, key control; use of survey meters and dosimeters; record keeping;

control of labels, marks and notices; communication with the client; control of environmental impact; movement of sources within the applicant's or client's premises; and periodical source inventory control.

(iii) Use of gauges on-site. Demonstrate that local rules and procedures include the acquisition of radiation survey meters, dosimeters, emergency kit, alarms, labels, marks and notices before going on-site; acquisition of sources from the storage; transport of sources; site management (including cooperation with the client); preparation of the site where gauges will be used (including selection of barriers, marking and posting); control of the controlled area and management of the supervised area (managing exposure of workers and members of the public); control of the position of sources; and informing workers not occupationally exposed.

PROTECTION OF THE PUBLIC

System of protection and safety for members of the public:

(1) Describe a system of protection and safety for members of the public. Demonstrate that optimization of radiation protection of the public is in place.

(2) Demonstrate that assessment, control and surveillance of the external exposure of the public are implemented, i.e. use of dose constraints for members of the public. Provide the assumptions used to assess the external exposure of the public.

(3) Describe the training of personnel having functions relevant to the protection and safety of members of the public. Demonstrate that a monitoring programme and management of records are in place.

(4) Describe the use of signs, labels, marks and notices addressing members of the public. Confirm that these are in a language understood by members of the public.

SECURITY PLAN

(1) Assignment of radioactive material to a category and a security level. Identify and explain the basis for the categorization of each radioactive material and its associated security level according to (article 95 of draft regulations).

(2) Site description. Describe the physical features of the site where the practice is conducted and its surrounding environment, including diagrams and scale floor and building drawings and photographs. This information must include:

(a) The site's surrounding environment, such as industrial, commercial, residential or other areas; distances to nearest police stations and other response services; proximity to other buildings and roads; and other features of security or operational interest, such as other facilities with hazardous materials.

(3) Operational description. Describe site operations in relation to the practice, including working and non-working hours; the number and type of staff involved in the site's operations; and the typical number, type and frequency of other people (such as visitors, public, customers, service personnel or contractors) who may be at the site during scheduled operations or at any other time.

(4) Security training and qualification. Provide the following information:

- (a) Training to be provided to each individual, including the required initial, specialized, advanced or refresher training for each position with security responsibilities; security awareness training for all staff; and other relevant, specific, on the job training, such as procedures and work instructions.
- (b) Provider(s) of the identified training and how frequently each part of the training must be conducted.
- (c) How training records that document satisfactory completion of all security related training are established and maintained.

(5) Access authorization. Describe the process used for authorizing personnel who need unescorted access to radioactive source locations, secured areas and or security sensitive information in order to perform their duties (which may or may not be directly related to security), including how the following functions are performed:

- (a) Identification of the positions requiring unescorted access;
- (b) Verification that individuals holding the identified positions are trustworthy;
- (c) Verification that individuals holding the identified positions have the necessary training;
- (d) Timely withdrawal of access for individuals who no longer require it;
- (e) Periodic review and re-evaluation for particular circumstances, such as withdrawing access authorization when personnel or positions no longer need unescorted access, transfer of job responsibilities or termination of employment;
- (f) Maintain up to date records of personnel authorized for unescorted access.

(6) Trustworthiness evaluation. Describe the process for evaluating the trustworthiness and reliability of personnel to determine whether they may be granted unescorted access to radioactive material, secured areas and/or security sensitive information, including the following:

- (a) Basis for identifying individuals whose trustworthiness must be evaluated for access authorization;
 - (b) Requirements regarding trustworthiness in applicable regulations or elsewhere, including any requirements that vary depending on security level or other factors;
- (c) Method by which each individual is evaluated;
- (d) Requirements for periodic review and any re-evaluation for particular circumstances;
- (e) Maintenance of records to document trustworthiness evaluations.

(7) Information protection. Describe the measures for protecting information from the unauthorized personnel of which could compromise the security of radioactive material.

(8) Maintenance programme. Describe the programme for maintaining security equipment to ensure continuous and reliable operation.

(9) Budget and resource planning. Describe how financial resources are allocated to the security of radioactive material.

(10) Evaluation for compliance and effectiveness. Describe the process used by the site to independently verify that the site is in compliance with all applicable security requirements, and for assessing the effectiveness of the security system in identifying any weaknesses that need to be corrected and any opportunities for continuous improvement, including arrangements for performance testing.

(11) Security system design. Describe how the security system has been designed to provide the level of protection required, taking into account the graded approach and principles of defence in depth and balanced protection. Indicate how each secured area and associated radioactive material are protected by detection, delay and response measures in an integrated and balanced way. Identify the types of equipment and systems installed and their location.

(12) Access control. Describe the physical measures for controlling access, including the following:

(a) How personnel are physically controlled at each control point to limit access only to authorized persons according to the access authorization procedure and to prevent unauthorized access;

(13) Procedures to be followed by authorized persons to access a secured area, including application of the two-person rule, where relevant.

(14) Procedures for routine, off-shift and emergency operations. Describe how assigned personnel, such as staff and contractors, operate security systems and discharge their other security related responsibilities during the following periods:

(a) Business hours;

(b) Non-business hours (off-shift or after hours, when staff are not ordinarily present, generally at nights, on weekends and during holidays);

(c) Emergency operations.

(15) Procedures for accounting and inventory. Describe how the site performs periodic accounting for radioactive material, including the following:

(a) Verification method used, such as a physical check, remote video monitoring, examination of seals or other tamper indicating devices, or radiation measurements.

(b) Records indicating the results of each verification, as well as when, by whom and by what method the verification was conducted.

(c) Requirements for corrective actions and reporting whether the presence of radioactive material cannot be verified. In addition, describe how the site establishes and maintains an inventory of its radioactive material.

(16) Procedures for receipt and transfer of radioactive material. Describe the procedures for ensuring that security and control of a radioactive source are maintained when it is being received from outside the site and when it is transferred to another authorized person.

(17) Response to a nuclear security event. Describe the arrangements with local law enforcement or other designated response authority for responding to a security event, including attempted or actual theft or sabotage of a radioactive source or device. (Attach evidence of agreement with any response authority.

(18) Communications. Describe the communication methods used to summon a response.

(19) Security event reporting. Describe how security events are reported to the operator's security organization. Describe how events are documented, who is responsible to document the event, and subsequent external reporting requirements.

(20) Security during emergencies and contingencies. Summarize arrangements and actions to be taken during non-security emergencies or other contingency situations to ensure that the protection of the radioactive material is maintained.